

REMARKS and ARGUMENTS

The Claims have been amended by amending Claims 1, 2, 51, and 52; by canceling Claims 3, 19, and 22-50; and by adding new Claims 53 and 54.

Claims 1, 2, 4-18, 20, 21, and 51-54 are pending in this application. Of the pending Claims, Claims 1, 2, 5-8, 20, 21, and 51-52 were rejected. Claims 4 and 9-18 were objected to for reasons of form as being dependent on a rejected base Claim, but were otherwise found to be allowable in substance.

The amendments to Claims 1, 2, and 51 cancel certain alternative limitations in those Claims.

Claim 1 has also been amended by incorporating the substance of Claim 19 as originally filed. Claim 19 has accordingly been canceled as being redundant.

The amendment to Claim 52 corrects a minor, self-evident typographical error (namely, the inadvertent omission of the left parenthesis in the third peptide sequence).

Basis for new Claim 53 is found throughout the specification, as well as in Claim 1 as originally filed, and in priority provisional application S.N. 60/412,081 at page 2. (The entire disclosure of the priority provisional application was incorporated by reference into the present specification. See paragraphs [0001] and [0101] of the present specification.)

The compound defined in new Claim 54 is the same as the compound defined in Claim 3 as originally filed. In view of the changes made to independent Claim 1, and the addition of new independent Claim 53, this subject matter now more logically depends from Claim 53 rather than from Claim 1. It is intended that the scope of new Claim 54 should be the same as the scope of Claim 3 as originally filed.

An additional copy of the Abstract has been provided at the Office's request. The Abstract attached as Appendix B is identical to the Abstract as originally filed. No changes have been made.

The sequence listings have been amended as shown in Appendix C and in the accompanying floppy disk. A clerical error has been corrected in SEQ ID NO: 4. No other changes were made in the sequence listings themselves; certain bibliographic information has been updated. See the discussion below for further explanation of the change in the sequence listings and in the bibliographic information.

Numerals in the headings below (e.g., "2" in the heading immediately below) refer to the corresponding sections of the July 22, 2005 Office Action.

2. Sequence Listings; and Statement under 37 C.F.R. §§ 1.821 (f) & (g)

The Office identified a discrepancy between SEQ ID NO:4 as defined in the Sequence Listings, and SEQ ID NO:4 as defined in the specification and Claims. The discrepancy apparently arose through a clerical error, for which the undersigned apologizes. As the July 22, 2005 Office Action correctly observed, the sequence as given in the specification and Claims was correct, while that in the Sequence Listings was in error. This discrepancy has been corrected in the revised sequence listings appearing in the paper copy in Appendix B, and in the accompanying floppy disk. SEQ ID NO:4 has been corrected in the Sequence Listings to conform to the sequence as given in the specification and Claims as originally filed, for example, in paragraph [0036] of the specification. No other changes have been made in the Sequence Listings themselves; however, the bibliographic information in fields <140> and <170> has been updated.

Statement under 37 C.F.R. §§ 1.821 (f) & (g). I, John H. Runnels, state over my signature and registration number appearing below that, to the best of my knowledge, information, and belief, the sequences contained in the enclosed computer readable sequence listings are the same as those contained in the paper copy attached below as Appendix C. Because the correction explained above merely conforms the sequences to those that appeared in the specification and Claims as originally filed, the revised sequence listings do not constitute new matter.

3. The Abstract

An additional copy of the Abstract has been provided at the Office's request. The Abstract attached as Appendix B is identical to the Abstract as originally filed. No changes have been made.

4. The Enablement Rejection

Claims 22-50 were rejected under 35 U.S.C. § 112, first paragraph as lacking an enabling disclosure.

Claims 22-50 have been canceled, making this ground of rejection moot. Applicants reserve the right to pursue the canceled subject matter in one or more continuation applications.

5. The § 119(e) Priority Date

The Office has acknowledged that Claims 3 and 24 as originally filed were entitled to the benefit of the provisional priority date, while taking the position that the other Claims as originally filed were not. Claim 24 has been canceled. Claim 3 as originally filed corresponds to new Claim 54. The Office should therefore presumably agree that at least Claim 54 is entitled to the benefit of the provisional priority date.

Likewise, new Claim 53 is clearly supported by the disclosure appearing at page 2 of the provisional priority application, so Claim 53 is also plainly entitled to the benefit of the provisional priority date.

Thus at least Claims 53 and 54 are entitled to the benefit of the priority provisional filing date.

Applicants do not concede that the remaining Claims are not also entitled to the benefit of the provisional filing date. Applicants reserve the right to demonstrate such priority at a later date, should the need arise. However, it is respectfully submitted that it is not necessary to decide this question for the time being. With the exception of Claims 53 and 54, in the discussion below it will be assumed for the sake of argument that the Claims might only be entitled to the benefit of the later nonprovisional filing date. Even if one makes this assumption, for the reasons given below it is respectfully submitted that all grounds of rejection should be withdrawn.

In sum, it is respectfully submitted that the question of priority is not currently an issue for any Claims other than Claims 53 and 54; and that Claims 53 and 54 are clearly entitled to the benefit of the provisional priority filing date.

Preliminary Note Concerning the Novelty of the Independent Claims

Claims 1 and 53 are the two independent Claims. If the independent Claims are novel and nonobvious, it logically follows that the dependent Claims are necessarily novel and nonobvious as well. See M.P.E.P. § 2143.03, first paragraph. Therefore, the following discussion of novelty generally focuses on Claims 1 and 53. However, Section 7 also addresses Claim 54, because Claim 54 corresponds to Claim 3 as originally filed, and the July 22, 2005 office action had entered a separate § 102(a) ground of rejection against original Claim 3.

7. *Organic Letters* §§ 102(b) and 102(a) Rejections

Claims 1, 2, 7, 8, 19, 20, 51, and 52 were rejected over the *Fu et al. Organic Letters* paper as being anticipated under 35 U.S.C. § 102(b). Claim 3 was rejected as being anticipated by the same paper under 35 U.S.C. § 102(a).

Claim 19 has been canceled.

This rejection was based on the disclosure on page 239 of the *Organic Letters* paper of a peptide that corresponds to SEQ ID NO:4 of the present application.

The alternative limitation of Claim 1 that would have encompassed SEQ ID NO:4 has been deleted. The remaining alternative limitations of Claim 1 do not encompass SEQ ID NO:4. Conforming changes have also been made to dependent Claims 2 and 51. As amended, Claim 1 and its dependent Claims do not read on SEQ ID NO: 4, and are therefore novel over the *Organic Letters* paper.

As previously discussed, Claims 53 and 54 are entitled to the benefit of the September 19, 2002 provisional priority date. Original Claim 3, corresponding to new Claim 54, was rejected as being anticipated by the *Organic Letters* paper under 35 U.S.C. § 102(a). The Applicants offer a rebuttal argument that should pre-empt a hypothetical future § 102(a) rejection of Claims 53 and 54 over the same reference.

Because the September 19, 2002 priority date is less than one year after the December 22, 2001 web publication date of the *Organic Letters* paper (see the bottom of page 237 of that paper), that paper may be removed as a reference against Claims 53 and 54 by showing that it is, at least in pertinent part, a publication of the inventors' own work. See the accompanying Affidavit of inventor Robert P. Hammer, particularly paragraph 5.

It is respectfully submitted that the Hammer Affidavit removes the *Organic Letters* paper as a reference against Claims 53 and 54.

It is respectfully submitted that both the § 102(a) and the § 102(b) rejections based on the *Organic Letters* paper have been overcome.

8. *Journal of Organic Chemistry* § 102(b) Rejection

Claims 1, 19, and 52 were rejected over the Fu *et al.* *Journal of Organic Chemistry* paper as being anticipated under 35 U.S.C. § 102(b).

Claim 19 has been canceled.

This rejection was based on the disclosure in Fig. 3A of the *Journal of Organic Chemistry* paper of the peptide Lys-Dbg-Ala-Dpg-Glu-NH₂.

This peptide does not satisfy the limitations of parts (a) and (b) of independent Claim 1. In particular, the Office has not identified an amyloid aggregation-inducing sequence for which the recited X and Y amino acids “are identical or homologous to alternating amino acids of the aggregation-inducing sequence of the amyloid protein or amyloid peptide.”

The peptide Lys-Dbg-Ala-Dpg-Glu-NH₂ is not an analog of, nor is it homologous to, any known amyloid-inducing sequence. The homologous sequence of naturally-occurring amino acids would be Lys-Phe-Ala-Ala-Glu. A search of the Swiss-Prot database shows this pentapeptide as being part of the sequence of a putative threonyl-tRNA synthetase from *Streptomyces avermitilis*, derived from its genome sequence as reported by H. Ikeda *et al.*, “Complete genome sequence and comparative analysis of the industrial microorganism *Streptomyces avermitilis*,” *Nature Biotechnology*, vol. 21, pp. 526-531 (2003). This protein has not been reported to have amyloid-inducing properties. Because this peptide does not satisfy the limitations of parts (a) and (b) of independent Claim 1, the *Journal of Organic Chemistry* paper does not anticipate the claimed inventions.

This is not a case, as suggested at page 7 of the July 22, 2005 Office Action, of the “discovery of a new property or use for a previously known compound” Rather, it is simply the case that the compound cited by the Office from the *Journal of Organic Chemistry* paper falls outside the scope of the Claim limitations. The *Journal of Organic Chemistry* paper does not anticipate the claimed inventions.

It is respectfully submitted that this ground of rejection should be withdrawn.

9. Dissertation § 102(a) Rejection

Claims 1-3, 6-8, 19-21, 51, and 52 were rejected over the Fu Dissertation as being anticipated under 35 U.S.C. § 102(a).

Claims 3 and 19 have been canceled.

It appears that the July 22, 2005 Office Action included original Claim 3 (corresponding to new Claim 54) in this ground of rejection due to a clerical error or oversight. The Office Action acknowledged that Claim 3, at least, was entitled to the benefit of the September 19, 2002 provisional filing date. As the Dissertation shows on its face, the Dissertation was submitted after the priority date, in December 2002, and should have then become publicly available sometime later. Thus the Dissertation is not a reference that may properly be cited against original Claim 3 (corresponding to new Claim 54).

Because the September 18, 2003 filing date of the present application is less than one year after the December 2002 submission date of the Dissertation, the Dissertation may be removed as a reference against all Claims in this application by showing that it is, at least in pertinent part, a publication of the inventors' own work. See the accompanying Affidavit of inventor Robert P. Hammer, particularly paragraph 6. It is respectfully submitted that the Hammer Affidavit removes the Dissertation as a reference.

It is respectfully submitted that the § 102(a) rejections based on the Dissertation have been overcome. Strictly in the alternative, it is respectfully submitted that no analogous rejection should be entered against Claims 53 and 54, both of which are entitled to the benefit of a priority date that is earlier than the Dissertation's date of publication.

10. § 102(a) Rejection based on Aucoin Presentation

Claims 1-3, 5, 7, 8, 19-21, 51, and 52 were rejected over the Aucoin Presentation as being anticipated under 35 U.S.C. § 102(a).

Claims 3 and 19 have been canceled.

It appears that the July 22, 2005 Office Action included original Claim 3 (corresponding to new Claim 54) in this ground of rejection due to a clerical error or

oversight. The Office Action acknowledged that Claim 3, at least, was entitled to the benefit of the September 19, 2002 provisional filing date. The Aucoin Presentation was given in March 2003, after the priority date. Thus the Office has essentially acknowledged that the Aucoin Presentation is not a reference that may properly be cited against original Claim 3 (corresponding to new Claim 54).

Applicants do not concede that the Aucoin Presentation may properly be cited against this application under any subsection of 35 U.S.C. § 102. However, for the time being it will be assumed for the sake of argument that it might be a potential reference under § 102(a). Even with this assumption, for the reasons given below it is respectfully submitted that this ground of rejection should be withdrawn. Applicants reserve the right to argue at a later date that the Aucoin Presentation is not a proper § 102(a) reference. However, it is respectfully submitted that it is not necessary to decide this question for the time being.

Because the September 18, 2003 filing date of the present application is less than one year after the March 2003 date of the Aucoin Presentation, the Presentation may be removed as a reference against all Claims in this application by showing that it represents, at least in pertinent part, the inventors' own work. See the accompanying Affidavit of inventor Robert P. Hammer, particularly paragraph 7. It is respectfully submitted that the Hammer Affidavit removes the Aucoin Presentation as a potential reference.

It is respectfully submitted that the § 102(a) rejections based on the Aucoin Presentation have been overcome. Strictly in the alternative, it is respectfully submitted that no analogous rejection should be entered against Claims 53 and 54, both of which are entitled to the benefit of a priority date that is earlier than the date of the Aucoin Presentation.

11. § 102(e) Rejection based on Soto-Jara

Claims 1, 7, 8, 21, 22, 28, 29, 42-50, and 52 were rejected over the Soto-Jara patent as being anticipated under 35 U.S.C. § 102(e).

Claims 22, 28, 29, and 42-50 have been canceled.

Applicants do not concede that the Soto-Jara patent is prior art against the present application under 35 U.S.C. § 102(e). However, for the time being it will be assumed, for

the sake of argument, that it might arguably be a potential reference under § 102(e). Even if one makes this assumption, for the reasons given below it is respectfully submitted that this ground of rejection should be withdrawn. Applicants reserve the right to argue at a later date that the Soto-Jara patent is not in fact prior art under 35 U.S.C. § 102(e). However, it is respectfully submitted that it is not necessary to decide this question for the time being.

This rejection was based on the disclosure in Soto-Jara of the peptide Leu-Aib-Phe-Phe-Asp. See, e.g., Soto-Jara's Claim 23.

Claim 1, the independent Claim in this group of Claims, has been amended to require that "at least two of Y_{AA1} , Y_{AA2} , and Y_{AA3} are $C^{\alpha,\alpha}$ -disubstituted amino acids" By contrast, the cited Soto-Jara peptide Leu-Aib-Phe-Phe-Asp has only one $C^{\alpha,\alpha}$ -disubstituted amino acid, namely the single Aib residue. Thus Soto-Jara does not anticipate the claimed inventions.

It is respectfully submitted that this ground of rejection has been overcome.

Miscellaneous

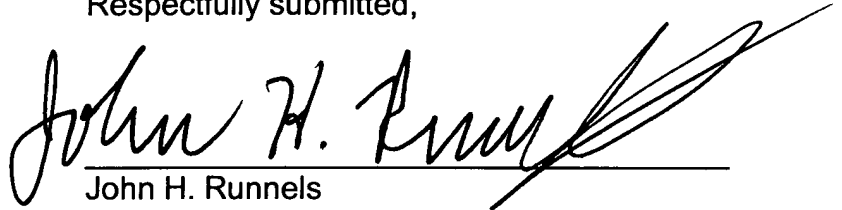
A supplemental Information Disclosure Citation is enclosed. The pertinence of the cited abstract is explained in the enclosed affidavit of Robert Hammer. The pertinence of the cited *Nature Biotechnology* paper is explained in section 8 above.

Conclusion

The Office is respectfully requested to return an initialed copy of the enclosed supplemental Information Disclosure Citation with the next communication concerning this application.

Allowance of Claims 1, 2, 4-18, 20, 21, and 51-54 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels", is written over a horizontal line. The signature is stylized with a large, sweeping flourish at the end.

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